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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/894,018 | 06/27/2001 | Alessandro Sette | 2060.0320003 | 7107 |

26111 7590 08/10/2004

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

MARSCHER, ARDIN H

| | |
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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,018

Applicant(s)

SETTE ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32, 34-36 and 58-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32, 34-36, and 58-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 5/24/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 27-32, 34-36, and 58-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been amended into the claims summarized as follows.

In claim 27, part (ii), (b), a generic spacer is introduced without any limitation as to the type of spacer. This contrasts with claim 27, as filed, at part (iii), wherein the spacer is required to prevent the "occurrence of a CTL or HTL junctional epitope". This broadening of spacer practice without such a prevention limitation adds NEW MATTER. Consideration of the written support pointed to by applicants fails to reveal generic support for the broadened spacer practice as now present in claim 27. For example, in the specification on page 17, lines 8-17, as pointed to by applicants the inserting of a spacer further prevents the occurrence of junctional epitopes. Similarly, in the specification on page 19, line

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18, through page 20, line 7, specifically on page 19, lines 18-20, also prevents said occurrence of a junctional epitope. None of the other citations pointed to by applicants support the broadened spacer limitation as now claimed. This NEW MATTER is also present in the other independent claims 28, 72, and 73 which are under examination. Claims which depend directly or indirectly from the above independent claims also contain this NEW MATTER due to their dependencies. This rejection is necessitated by amendment.

In claim 27, part (i), a selecting step has been added directed to selecting two or more CTL epitopes. This contrasts with claim 27, as filed, at part (i), wherein sorting of CTL epitope nucleic acids is recited. This adding of a new step is NEW MATTER because written support for this has not been found as filed. Consideration of the written support pointed to by applicants fails to reveal support for said added step as now present in claim 27. For example, in the specification on page 56, lines 11-13, as pointed to by applicants, the selection of epitopes is directed to epitopes that contain HLA allele-specific motifs or supermotifs and not the now claim 27 CTL epitopes. This is the closest citation to the present step (i) of instant claim 27. None of the other citations pointed to by applicants support the added step limitation as now claimed. This NEW MATTER is also similarly present in the other independent claims 28, 72, and 73 which are under examination as now including selecting steps which have not been found as filed regarding written basis. Claims which depend directly or indirectly from the above independent claims also contain this NEW MATTER due to their dependencies. This rejection is necessitated by amendment.

Claim 60, newly submitted, contains NEW MATTER because the predicting practice is broadened over claim 37 as filed, cited for support. It is noted that there is no predicting practice in the page 50-52 citation pointed to by applicants. The predicting practice of claim 37 as originally filed includes the limitations of a selecting step as now in claim 59, part (ii), but not in claim 60 which therefore is broadened over claim 37 as filed and therefore contains NEW MATTER. This rejection is necessitated by amendment.

Newly added claims 62 and 63 have newly added NEW MATTER via the selecting step (i) and the broadened spacer step (ii), (b), as also contained in the corresponding steps in claim 27 as described above. This rejection is necessitated by amendment.

CORRECTION OF INVENTORSHIP

In view of the papers filed 5/24/04, the inventorship in this nonprovisional application has been changed by the deletion of David H. Brown.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 7, 2004

 8/7/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER